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The Standards for Marketing Approval of Vitamin Preparations

1. Scope of Vitamin Preparations

Vitamin Preparations, as defined here, are oral vitamin preparations which contain one or more vitamins for the purpose of alleviating symptoms against which such a vitamin should be effective or for vitamin supplementation.

2. Standards

The following standards shall be applied to Vitamin Preparations.

For vitamin preparations which do not conform to these standards, the submission of documents regarding the efficacy, safety, and the basis for combination shall be required for review.

(1) Types of Active Ingredients

- A) The types of active ingredients which may be combined in vitamin preparations are listed in the attached Table 1.
- B) For preparations mainly consisting of the active ingredients listed in Column I of the attached Table 1 (hereinafter referred to as Vitamin A preparations), those mainly consisting of the active ingredients in Group 1 may include the active ingredients listed in Column II or IV of the same Table and those mainly consisting of the active ingredients in Group 2 may include the active ingredients in Group 1 of Column I, Column III, IV, or VIII.
- C) Preparations mainly consisting of the active ingredients listed in Column II of the attached Table 1 (hereinafter referred to as Vitamin D preparations) may include the active ingredients listed in Group 1 of Column I, Column III, VIII, or Group 7 of Column X of the same Table.
- D) Preparations mainly consisting of the active ingredients listed in Column III of the attached Table 1 (hereinafter referred to as Vitamin E preparations) may include the active ingredients listed in Column IV, Group 2 of Column V, Column VI, VII, VIII, Group 1 or 2 of Column IX, Group 2, 3, 6, or 9 of Column X, or Group 1 or 2 of Column XI of the same Table.
- E) Preparations mainly consisting of the active ingredients listed in Column IV of the attached Table 1 (hereinafter referred to as Vitamin B1 preparations) may include the active ingredients listed in Column III, V, VI, VII, Group 1 or 2 of Column IX, Group 1, 6, or 9 of Column X, or Group 1 of Column XI of the same Table.
- F) Preparations mainly consisting of the active ingredients listed in Column V of the attached Table 1 (hereinafter referred to as Vitamin B2 preparations) may include the active ingredients listed in Column IV, VI, VIII, IX, Group 4, 5, 6, or 8 of Column X, or Group 3 of Column XI of the same Table.
- G) Preparations mainly consisting of the active ingredients listed in Column VI of the attached Table 1 (hereinafter referred to as Vitamin B6 preparations) may include the active ingredients listed in Column III, IV, V, VII, VIII, IX, Group 4, 5, 6, or 8 of Column X, or Group 3 of Column XI of the same Table.
- H) Preparations mainly consisting of the active ingredients listed in Column VIII of the attached Table 1 (hereinafter referred to as Vitamin C preparations) may include the active ingredients listed in Column III, V, VI, IX, or Group 4, 5, or 8 of Column X of the same Table.
- I) Preparations mainly consisting of the active ingredients in Group 1 of Column I and Column II of the attached Table 1 (hereinafter referred to as Vitamin A and D preparations) may include the active ingredients listed in Column III, IV, VIII, or Group 7 of Column X of the same Table.
- J) Preparations mainly consisting of the active ingredients listed in Columns V and VI of the attached Table 1 (hereinafter referred to as Vitamin B2 and B6 preparations) may include the

active ingredients listed in Column VIII, IX, Group 4, 5, or 8 of Column X, or Group 3 of Column XI of the same Table.

- K) Preparations mainly consisting of the active ingredients listed in Columns III and VIII of the attached Table 1 (hereinafter referred to as Vitamin E and C preparations) may include the active ingredients listed in Group 2 of Column V, Column VI, Group 1 or 2 of Column IX, or Group 3 of Column X of the same Table.
- L) Preparations mainly consisting of the active ingredients listed in Columns IV, VI, and VII of the attached Table 1 (hereinafter referred to as Vitamin B1, B6 and B12 preparations) may include the active ingredients listed in Column III, Group 1 or 2 of Column IX, or Group 6 of Column X of the same Table.
- M) If active ingredients from Column II, III, IV, V, VI, or VII of the attached Table 1 are combined, only one active ingredient from each column may be used.
- N) If active ingredients from Column VIII of the attached Table 1 are combined, no more than 2 active ingredients from the column may be used.
- O) If active ingredients from Column I, IX, or Group 4 or 8 of Column X of the attached Table 1 are combined, only one active ingredient from each column or group may be used.

(2) Quantities of active ingredients

- A) When the active ingredients in the attached Table 1 are used as the main ingredients of vitamin preparations, the maximum daily dose, minimum daily dose, maximum single dose, and minimum single dose shall be those given in Section A of the Table.
- B) When the active ingredients in the attached Table 1 in vitamin preparations are used as active ingredients other than the main vitamins, the maximum daily dose, minimum daily dose, and maximum single dose shall be those given in Section B of the Table.
- C) When 2 of the active ingredients in Column I or VIII of the attached Table 1 are combined or when 2 or more of the active ingredients in Group 7 of Column X are combined, the sum of the values obtained by dividing the amounts of each active ingredient used by their respective maximum daily dose shall not exceed one, or the sum of the values obtained by dividing the amounts of each active ingredient used by their respective minimum daily dose should be at least one.

(3) Dosage forms

The dosage forms of vitamin preparations shall be capsules, granules, pills, powders, electuaries, tablets, jelly type drops, or oral liquids.

(4) Dosage and administration

- A) In principle, the dosage of vitamin preparations shall not exceed 3 doses a day.
- B) Dosage and administration suggesting that the preparations may be given to infants less than 3 months of age are not permitted.
- C) Hard capsules and soft capsules, pills or tablets over 6 mm in diameter intended to be taken by children less than 5 years old are not permitted.
- D) Soft capsules, pills or tablets not more than 6 mm in diameter intended to be taken by children less than 3 years old are not permitted.
- E) The maximum and minimum daily and single doses for people under 15 years of age shall be calculated by multiplying the maximum and minimum daily and single doses shown in the attached Table 1 by the values specified in the Coefficient column for the corresponding age ranges in the attached Table 2.

(5) Indications

The indications of vitamin preparations should be within the scope of the attached Table 3.

Attached Table 1

Classif ication			A		B		Remarks
			Maximum daily dose	Minimum daily dose	Maximum daily dose	Minimum daily dose	
Column I	Group 1	Retinol acetate	4,000I.U.	2,000I.U.	2,000I.U.	500I.U.	as vitamin A
		Retinol palmitate	4,000I.U.	2,000I.U.	2,000I.U.	500I.U.	as vitamin A
		Vitamin A oil	4,000I.U.	2,000I.U.	2,000I.U.	500I.U.	as vitamin A
	Group 2	Cod liver oil	4,000I.U.	2,000I.U.	2,000I.U.	500I.U.	as vitamin A
		Strong cod liver oil	4,000I.U.	2,000I.U.	2,000I.U.	500I.U.	as vitamin A
Column II		Ergocalciferol	400I.U.	200I.U.	200I.U.	50I.U.	as vitamin D
		Cholecalciferol	400I.U.	200I.U.	200I.U.	50I.U.	as vitamin D
Column III		<i>d</i> - α -Tocopherol succinate	300mg (100mg)	100mg (50mg)	100mg	10mg	as <i>dl</i> - α -tocopherol succinate
		<i>dl</i> - α -Tocopherol succinate	300mg (100mg)	100mg (50mg)	100mg	10mg	
		<i>dl</i> - α -Tocopherol calcium succinate	300mg (100mg)	100mg (50mg)	100mg	10mg	
		<i>d</i> - α -Tocopherol acetate	300mg (100mg)	100mg (50mg)	100mg	10mg	
		<i>dl</i> - α -Tocopherol acetate	300mg (100mg)	100mg (50mg)	100mg	10mg	
		<i>d</i> - α -Tocopherol	300mg (100mg)	100mg (50mg)	100mg	10mg	
		<i>dl</i> - α -Tocopherol	300mg (100mg)	100mg (50mg)	100mg	10mg	
Column IV	Group 1	Thiamine hydrochloride	30mg (10mg)	1mg (1mg)	25mg (10mg)	1mg	
		Thiamine nitrate	30mg (10mg)	1mg (1mg)	25mg (10mg)	1mg	
		Bisthiamine nitrate	30mg (10mg)	1mg (1mg)	25mg (10mg)	1mg	as thiamine disulfide
		Thiamine disulfide	30mg (10mg)	1mg (1mg)	25mg (10mg)	1mg	
		Thiamine dicetylsulfate	30mg (10mg)	1mg (1mg)	25mg (10mg)	1mg	as thiamine nitrate or thiamine hydrochloride
	Group 2	Dicethiamine hydrochloride	100mg	5mg	25mg	1mg	as thiamine hydrochloride
		Fursultiamine hydrochloride	100mg	5mg	25mg	1mg	as fursultiamine
		Octotiamine	100mg	5mg	25mg	1mg	
		Cycothiamine	100mg	5mg	25mg	1mg	
		Bisibuthiamine	100mg	5mg	25mg	1mg	
		Bisbentiamine	100mg	5mg	25mg	1mg	as thiamine hydrochloride
		Fursultiamine	100mg	5mg	25mg	1mg	
		Prosultiamine	100mg	5mg	25mg	1mg	
		Benfotiamine	100mg	5mg	25mg	1mg	as thiamine hydrochloride
Column V	Group 1	Flavin adenine dinucleotide sodium	45mg	5mg	12mg	2mg	as flavin adenine dinucleotide
		Riboflavin	30mg	2mg	12mg	2mg	
		Riboflavin sodium phosphate	30mg	2mg	12mg	2mg	as riboflavin
	Group 2	Riboflavin butyrate	20mg	5mg	12mg	2mg	

Column VI		Pyridoxine hydrochloride	100mg	10mg	50mg	5mg	
		Pyridoxal phosphate	60mg	10mg	50mg	5mg	
Column VII		Hydroxocobalamin hydrochloride	1,500µg	60µg	60µg	1µg	as hydroxocobalamin
		Hydroxocobalamin acetate	1,500µg	60µg	60µg	1µg	as hydroxocobalamin
		Cyanocobalamin	1,500µg	60µg	60µg	1µg	
		Hydroxocobalamin	1,500µg	60µg	60µg	1µg	
Column VIII		Ascorbic acid	2,000mg	50mg	500mg	50mg	as ascorbic acid
		Calcium ascorbate	2,000mg	50mg	500mg	50mg	
		Sodium ascorbate	2,000mg	50mg	500mg	50mg	as ascorbic acid
Column IX	Group 1	Nicotinic acid			60mg	12mg	
		Nicotinamide			60mg	12mg	
	Group 2	Panthenol			30mg	5mg	
		Calcium pantothenate			30mg	5mg	
		Sodium pantothenate			30mg	5mg	
	Group 3	Biotin			500µg	10µg	
Column X	Group 1	Mixture of potassium aspartate and magnesium aspartate (equal mixture)			400mg	200mg	
	Group 2	Inositol hexanicotinate			400mg	80mg	
	Group 3	Ursodeoxycholic acid			60mg	10mg	
	Group 4	L-Cysteine hydrochloride			160mg	30mg	
		L-Cysteine			160mg	30mg	
	Group 5	Orotic acid			200mg	60mg	
	Group 6	γ-Oryzanol			10mg	5mg	
	Group 7	Calcium glycerophosphate			300mg	30mg	as calcium
		Calcium gluconate			300mg	30mg	as calcium
		Precipitated calcium carbonate			300mg	30mg	as calcium
		Calcium lactate			300mg	30mg	as calcium
		Anhydrous dibasic calcium phosphate			300mg	30mg	as calcium
		Dibasic calcium phosphate			300mg	30mg	as calcium
	Group 8	Glucuronolactone			1,000mg	200mg	
		Glucuronamide			1,000mg	200mg	
	Group 9	Sodium chondroitin sulfate			900mg	180mg	

Column XI	Group 1	Processed Garlic Bulb			200mg	20mg	
	Group 2	Ginseng	Extract (Crude drug conversion value)		3g	0.6g	
			Powder		1.5g	0.3g	
	Group 3	Coix seeds	Extract (Crude drug conversion value)		10g	1g	
			Powder		3g	0.3g	

(Note) The figures in parentheses in the maximum daily dose or minimum daily dose columns indicate the maximum or minimum single dose, respectively.

Attached Table 2

Age	Coefficient	
15 years old and over	1	(1)
11 years old-Under 15	2/3	(2/3)
7 years old-Under 11	1/2	(2/3)
3 years old-Under 7	1/3	(1/2)
1 year old-Under 3	1/4	(1/2)
6 months-Under 1	1/5	(1/2)
3 months-Under 6 months	1/6	(1/2)

(Note) The coefficients in parentheses are used for the active ingredients in Columns I and II for vitamins A, D, and A and D preparations.

Attached Table 3

Preparations		Indications
Vitamin A preparations	Preparations with Group 1 ingredients	Relief of the following symptoms: dryness of the eyes Night blindness (nyctalopia) Supplementation of Vitamin A in the following cases: during pregnancy and lactation, decreased strength during and after illness, and for growing children
	Preparations with Group 2 ingredients	Relief of the following symptoms: dryness of the eyes Night blindness (nyctalopia) Supplementation of Vitamin A and D in the following cases: during pregnancy and lactation, decreased strength during and after illness, and for growing children and the elderly
Vitamin D preparations		To treat bone and teeth developmental defects Prevention of rickets Supplementation of Vitamin D in the following cases: during pregnancy and lactation, and for growing children and the elderly

Preparations	Indications
Vitamin E preparations	Relief of the following symptoms due to peripheral circulatory disturbances: stiffness in the shoulder and neck, numbness/chills in the limbs and chilblains Relief of the following symptoms in the climacterium: stiffness in the shoulder and neck, chills, numbness in the limbs and hot flashes, irregular menstruation (A physician or pharmacist should be consulted if there is no improvement after about one month of administration) Supplementation of Vitamin E in the following case: for the elderly
Vitamin B ₁ preparations	Relief of the following symptoms: neuralgia, muscle and joint pain (lumbago, stiff shoulder, frozen shoulder), numbness in the limbs, constipation, and eye strain Beriberi (A physician or pharmacist should be consulted if there is no improvement after about one month of administration) Supplementation of Vitamin B ₁ in the following cases: physical fatigue, during pregnancy and lactation, decreased strength during and after illness
Vitamin B ₂ preparations	Relief of the following symptoms: angular stomatitis, canker sores, stomatitis, glossitis, eczema, dermatitis, rash, sores, acne, skin roughness, rosacea, congestion of the eye, and itchy eyes (A physician or pharmacist should be consulted if there is no improvement after about one month of administration) Supplementation of Vitamin B ₂ in the following cases: physical fatigue, during pregnancy and lactation, and decreased strength during and after illness
Vitamin B ₆ preparations	Relief of the following symptoms: angular stomatitis, canker sores, stomatitis, glossitis, eczema, dermatitis, rash, sores, acne, skin roughness, and numbness in the limbs (A physician or pharmacist should be consulted if there is no improvement after about one month of administration) Supplementation of Vitamin B ₆ in the following cases: during pregnancy and lactation, and decreased strength during and after illness
Vitamin C preparations	Relief of the following symptoms: spots, freckles, and pigmentation due to sunlight/rash Prevention of bleeding in the following cases: bleeding of the gums and nose bleeds (A physician, pharmacist, or dentist should be consulted if there is no improvement after about one month of administration) Supplementation of Vitamin C in the following cases: physical fatigue, during pregnancy and lactation, decreased strength during and after illness, and for the elderly
Vitamin A and D preparations	Relief of the following symptoms: dryness of the eyes Bone and teeth developmental defects Night blindness (nyctalopia) Prevention of rickets Supplementation of Vitamin A and D in the following cases: during pregnancy and lactation, decreased strength during and after illness, and for growing children and the elderly
Vitamin B ₂ and B ₆ preparations	Relief of the following symptoms: angular stomatitis, canker sores, stomatitis, glossitis, eczema, dermatitis, rash, sores, acne, and skin roughness (A physician or pharmacist should be consulted if there is no improvement after about one month of administration) Supplementation of Vitamin B ₂ and B ₆ in the following cases: physical fatigue, during pregnancy and lactation, and decreased strength during and after illness

Preparations	Indications
Vitamin E and C preparations	<p>Relief of the following symptoms due to peripheral circulatory disturbances: stiffness in the shoulder and neck, numbness/chills in the limbs and chilblains</p> <p>Relief of the following symptoms: spots, freckles, and pigmentation due to sunlight/rash</p> <p>Prevention of bleeding in the following cases: bleeding of the gums and nose bleeds (A physician, pharmacist, or dentist should be consulted if there is no improvement after about one month of administration)</p> <p>Supplementation of Vitamin E and C in the following cases: physical fatigue, decreased strength during and after illness, and for the elderly</p>
Vitamin B ₁ , B ₆ , and B ₁₂ preparations	<p>Relief of the following symptoms: neuralgia, muscle and joint pain (lumbago, stiff shoulder, frozen shoulder), numbness in the limbs, and eye strain</p> <p>(A physician or pharmacist should be consulted if there is no improvement after about one month of administration)</p> <p>Supplementation of Vitamin B₁, B₆, and B₁₂ in the following cases: physical fatigue, during pregnancy and lactation, and decreased strength during and after illness</p>